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08/192,336 02/04/94 HUANG

W ETH926  
EXAMINER

18N2/0324

WHITE, E

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ART UNIT PAPER NUMBER

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1815  
DATE MAILED:

03/24/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined  Responsive to communication filed on 2/14/1994  This action is made final.A shortened statutory period for response to this action is set to expire Three month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1.  Notice of References Cited by Examiner, PTO-892.
2.  Notice of Draftsman's Patent Drawing Review, PTO-948.
3.  Notice of Art Cited by Applicant, PTO-1449.
4.  Notice of Informal Patent Application, PTO-152.
5.  Information on How to Effect Drawing Changes, PTO-1474..
6.

**Part II SUMMARY OF ACTION**1.  Claims 1 - 17 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2.  Claims \_\_\_\_\_ have been cancelled.3.  Claims \_\_\_\_\_ are allowed.4.  Claims 1 - 8 and 13 - 17 are rejected.5.  Claims 9 - 12 are objected to.6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.8.  Formal drawings are required in response to this Office action.9.  The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are  acceptable;  not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been  approved by the examiner;  disapproved by the examiner (see explanation).11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved;  disapproved (see explanation).12.  Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has  been received  not been received  been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.14.  Other

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Claims 1-17 are pending in the instant application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8 and 13-16 are rejected under 35 U.S.C.

§ 102(b) as being clearly anticipated by Galatik et al (Czechoslovak Patent No. 264,719, see translated copy).

The Galatik et al Patent discloses a pharmacological preparation which contains a complex of a hyaluronate of an alkali metal with a multivalent cation selected from the group Mg<sup>2+</sup>, Ca<sup>2+</sup>, Zn<sup>2+</sup>, Ba<sup>2+</sup>, Al<sup>3+</sup>, Cu<sup>2+</sup>, Zr<sup>4+</sup>, Cr<sup>3+</sup>, Fe<sup>3+</sup>, alone or in a mixture with physiological salt solution, where the molar composition of the complex is 0.1 to 5 moles of the hyaluronate to 1 to 25 moles of the coordinated cation (see page 2, last paragraph of the translated copy). The Galatik et al Patent discloses the preparation as being used to prevent postoperative adhesion of tendons and conjunctival sacs (see page 2, 2nd paragraph of the translated copy) which clearly anticipates the claims of the instant application.

Applicant's arguments with respect to Claims 1-6, 8 and 13-16 have been considered but are deemed to be moot in view of the new grounds of rejection.

included in this action can be found in a prior Office action.

Claims 7 and 17 are rejected under 35 U.S.C. § 103 as being unpatentable over Galatik et al (Czechoslovak Patent No. 264,719, see translated copy) as applied to Claims 1-6, 8 and 13-16 above, and further in view of Balazs (US Patent No. 4,141,973) and Shimizu et al (US Patent No. 4,024,073).

As disclosed above, the Galatik et al Patent discloses a hyaluronate complex of an alkali metal with a multivalent cation selected from the group  $Mg^{2+}$ ,  $Ca^{2+}$ ,  $Zn^{2+}$ ,  $Ba^{2+}$ ,  $Al^{3+}$ ,  $Cu^{2+}$ ,  $Zr^{4+}$ ,  $Cr^{3+}$ ,  $Fe^{3+}$ , which can be used to prevent postoperative adhesion of tendons and conjunctival sacs. However, the Galatik et al Patent does not disclose information with regard to viscosity and administration of the hyaluronate complex.

The Balazs Patent discloses molecular weights of hyaluronic acid which are within the scope of the molecular weights of the hyaluronic acid disclosed in the specification and also suggests viscosity values of hyaluronic acid which are within the scope of the adhesion preventative disclosed in the instant claims. (see column 4, lines 44-57 of the Balazs Patent).

Shimizu et al disclose a hydrogel which comprises a water-soluble polymer containing a chelating agent bound to a polymer chain and a metal ion having a valance of 2 or above, whereby the polymers are cross-linked through chelation between two chelating agents by the polyvalent metal ion. Shimizu et al further disclose that the polymer may be selected as hyaluronic acid (see

column 1, lines 55 and 56). Shimizu et al disclose that the hydrogel-drug can be used in various ways which include injection and surgical use, which is within the scope of instant claim 7 whereby the adhesion preventative is applied directly to the site 5 of surgical trauma in one application by injection through a syringe.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to used the hyaluronate complex to prevent postoperative adhesion of tendons 10 and conjunctival sacs as disclosed by Galatik et al and to apply the hyaluronate complex by injection with a syringe as suggested by Shimizu et al and to used an adhesion preventative having a viscosity of 2,500 cps to about 250,000 cps since Balazs shows that hyaluronic acid having such viscosity values is well known 15 in the art.

Applicant's arguments with respect to Claims 7 and 17 have been considered but are deemed to be moot in view of the new grounds of rejection.

20 Claims 9-12 are rejected under 35 U.S.C. § 103 as being unpatentable over Galatik et al (Czechoslovak patent No. 264,719, see translated copy) as applied to claims 1-6 and 8 above, and further in view of Applicants's own disclosure at page 10, lines 15-27 of the specification.

25 Galatik et al is as discussed above. The specification at page 10 discloses that it is well known that tolmetin and other

NSAIDS are adhesion preventatives. Therefore, it would have been prima facie obvious to one of ordinary skill in the art to combine two compositions each one of which is taught by prior art to be useful for the same purpose in order to form a third 5 composition to be used for the same purpose, In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Applicant's arguments with respect to claims 9-12 are have been considered but are deemed to be moot in view of the new grounds of rejection.

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All the claims (1-17) are rejected.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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White  
March 14, 1995

  
MICHAEL G. WITSHYN  
SUPERVISORY PATENT EXAMINER  
GROUP 1800

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